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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,290	03/24/2004	Cindra A. Widrig Opalsky	215105.00608	3910
27160 7590 01/30/2008 PATENT ADMINISTRATOR KATTEN MUCHIN ROSENMAN LLP 1025 THOMAS JEFFERSON STREET, N.W. EAST LOBBY: SUITE 700 WASHINGTON, DC 20007-5201			EXAMINER ALEXANDER, LYLE	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 01/30/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,290	Applicant(s) OPALSKY ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-126 and 128-167 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-126 and 128-167 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 108, 119-121, 128-130 and 133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 step (d) is not clear if the sample is metered into another chamber. Step (f) is not clear if the sample is moved to a new location positioned near the sensor by the pump or if the sample remains at the position where it was mixed with the reagent. Clarification could be achieved by Applicants numbering the various chambers (e.g. a first holding chamber..., a second overflow chamber ..., a third holding chamber ..., a fourth analysis chamber ... etc.). Claim 167 is also unclear to locations the metering locations of the sample and could also be clarified by numbering the various chambers as suggested above.

Claim 108 does not appear to further limit the method of claim 90 because it is directed to the method of making the holding chamber and should be deleted. Clarification could be achieved by incorporating similar amendments that were made to claim 119.

Claim 120 does not appear to further limit the method of claim 90 because it is directed to the shape/size of the apparatus.

Claim 121 is not clear if it is a method or structural limitation. The claim could be clarified if "adding a predetermined amount or reagent in the holding chamber" were claimed.

Claims 128-129 are not clear how this further limits the method of claim 90 and what is the electrochemical species.

Claim 130 is not clear how this further limits the method of claim 90 and the locations where the enzyme substrates are located.

Claim 133 is not clear how this further limits the method of claim 90, what the matrix is or how dissolution is promoted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 90-126 and 128-167 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-107 and claims 1-47 of U.S. Patent No. 6,750,053 and 6,438,498 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because are directed to placing the sample in a holding chamber, metering off the overflow from the holding chamber, metering the sample to an analysis location, mixing the sample with a reagent, etc. The 6,750,053 patent is related to the instant application as a continuation and not as a divisional which is why the patent is available for this double patenting rejection (e.g. there was no restriction requirement made in the patent).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 90-105, 107, 109-118, 123, 131-135, 144-145 and 167 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Handique et al. (USP 6,130,098).

Handique et al. (USP 6,130,098) teach a method of detecting a reaction product where a sample is introduced into a holding chamber, excess sample removed, and reagents added and mixed. The resultant reaction is detection and the analyte of interest is quantified. There is a stop junction to control the fluid flow and a hydrophobic region. Handique et al. (USP 6,130,098) additionally teaches in columns 17-18 lines 63-68 respectively silicon dioxide surface and in column 26 line 20 teach a digestion buffer. Furthermore, column

16 lines 40+ teaches fluid control with sealed valves that have been read on the claimed "sealing the holding chamber with a ... after step(a)".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 124-126, 136-143 and 146-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique et al. (USP 6,130,098).

See the appropriate paragraph of the 8/22/07 Office action.

Response to Arguments

Applicant's arguments filed 11/28/07 have been fully considered but they are not persuasive.

Applicants' amendments and remarks were convincing to overcome the 35 USC 112 second paragraph rejections of claims 90.

The Office maintains the remainder of the 35 USC 112 second paragraph rejections is proper. The Office maintains base claim 90 is directed to a method and claims 108, 119-121, 128-130 and 133 are directed to a structural limitations which do not further limit the method of use.

Applicants state the 11/28/07 amendments obviate the Double Patenting rejections. Applicants have not provided any reasoning why the 11/28/07 amendments obviate these rejections. The Office has reconsidered the pending claims and maintains the Double Patenting rejections of record are proper.

Applicant's remarks concerning Besemer et al. were convincing.

On page 21 of the 11/28/07 response, Applicants state Handique et al. does not teach sealing of the chamber after the addition of the sample. Handique et al. teach in column 16 lines 40+ teaches fluid control with sealed valves that has been read on the claimed "sealing the holding chamber with a ... after step(a)".

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743

